REMARKS

The Office Action and the cited and applied reference have been carefully studied. No claim is allowed. Claims 11-30 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 1-10 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is obviated by the cancellation of the rejected claims without prejudice. New claims 11-21 replace the rejected claims and are not believed to be subject to the indefiniteness issues raised by the examiner. With regard to the term "physiologically active proteins", this is defined in the paragraph bridging pages 3 and 4 of the specification and is a commonly used term, as evidenced by the cited and applied Goodman et al. U.S. Patent No. 4,956,282 (see Summary of the Invention), which term is similar to the term "biologically active" protein or molecule that frequently appears in patents when referring to methods that can be used in general for producing a wide variety of "biologically or physiologically active" proteins. Accordingly, the term "physiologically active protein" is not indefinite.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1-10 have been rejected under 35 U.S.C. §102(b) as being anticipated by Goodman et al., U.S. Patent No. 4,956,282. This rejection is respectfully traversed.

While rejected claims 1-10 are now canceled without prejudice, this rejection is discussed as it might relate to the new claims added in place of the rejected claims.

It should be first noted that what is disclosed in Goodman is a method for producing an interferon, which comprises growing dicotyledonous plant cells containing an integrated sequence (see claim 1 of Goodman). Goodman states at column 1, lines 39-45:

> There therefore remains substantial interest in providing alternative economic systems for producing peptides, where high yields may be obtained and significantly, the products may be produced in a form providing for a high degree of physiological activity common to the wild-type peptide having the same or substantially the same amino acid sequence.

It is clear that Goodman utilizes plant cells merely as a biological factory. In fact, Goodman further states at column 5, lines 40-44, that:

> When the plants have been grown to the desired stage, the plants or plant parts, e.g., seeds, fruit or the like may be harvested, and the <u>desired product</u>

isolated in accordance with conventional ways. (emphasis added)

By contrast, the presently claimed invention provides a transgenic plant *per se* or an isolated tissue thereof or a processed form thereof rather than an isolated or purified protein. As disclosed at page 3, lines 3-16 of the specification, applicants found that the effectiveness of using transgenic plants an isolated tissue thereof or a processed formed thereof containing a physiologically active protein for oral administration was higher than using isolated preparations of the same physiologically active protein, purified at a level feasible for pharmaceutical uses. Based on these surprising findings, the inventors concluded that when animals ingest the transgenic plants containing physiologically active proteins of mammalian origin, the proteins exhibit a desirable efficacy in the animal. It is therefore a transgenic plant *per se* or an isolated tissue thereof or a processed form thereof that is provided in the presently claimed invention. Such a transgenic plant is obtainable, as defined in the amended claim 1, by (i) introducing a DNA sequence encoding a physiologically active protein into a plant protoplast, etc., and (ii) growing or regenerating the transformed plant protoplast, etc., while allowing expression of said DNA sequence within the transgenic plant body in an amount effective when taken orally to treat

humans or mammals suffering from diseases susceptible to said physiologically active protein.

New claims 22-30 are directed to a method for treating humans or mammals by administering a physiologically active protein to a human or mammal through ingestion of a transgenic plant, an isolated tissue thereof, or a processed form thereof containing an effective amount of the physiologically active protein.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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